



AL/3763  
Certificate of Express or First-Class Mailing  
I hereby certify that I have deposited this cor-  
respondence with the US Postal Service as  
first-class or, if a mailing-label number is given  
below, as express mail addressed to Comm. of  
Patents, Box 1450, Alexandria, VA 22313-1450  
on JAN 10 2007

22776

IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor Udo J. VETTER et al  
Patent App. 10/821,253  
Filed 8 April 2004  
For PREFILLED HYPODERMIC SYRINGE

Conf. No. 8401

Art Unit 3763  
Hon. Commissioner of Patents  
Box 1450  
Alexandria, VA 22313-1450

Examiner Ahmed, A

Appealed 11-Sep-06

SUBSTITUTE APPEAL BRIEF UNDER 37 CFR 41.37

In response to the second Notification of Noncompliant Appeal Brief mailed 05 January 2007, now come appellants by their duly authorized attorney and resubmit their brief under the provisions of 37 CFR 41.37.

I. REAL PARTY IN INTEREST

The real party in interest here is the assignee, Arzneimittel GmbH, via an assignment recorded 14 October 2004 at reel 015899 frame 0914.

## II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

## III. STATUS OF CLAIMS

The case has claims 1 - 4 of which only claim 1 is independent. Clean copies of the claims are attached in the Claim Appendix.

## IV. STATUS OF AMENDMENTS AFTER FINAL ACTION

An amendment after final action was entered. It made no changes to the claims and only argued the rejection. An Amendment on Appeal filed herewith corrects two minor obvious typographical errors in the dependent claims.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

The goal of the instant invention is to provided a hypodermic needle assembly of the disposable type that is constructed so that it can be sterilized in a relatively simple manner during automated assembly. The problem to be solved is that such disposable hypodermics are typically supplied to the user with a removable cap protecting the actual needle, but it is necessary

during manufacture to ensure that the interior of this cap and the needle are sterilized. This is typically done in the prior art by sterilizing the cap and needle when they are separate from each other and then to fit them together, a tricky procedure to do while maintaining sterility.

This problem is solved according to the invention by providing a cap which is movable between an outer position in which it is spaced from the needle so that a sterilizing fluid, e.g. steam, can get between the cap and the needle, and an inner position fitting snugly over and protecting the needle.

The needle assembly according to the invention therefore comprises, in the words of the claim 1 and as seen in the drawing:

a hollow body 1 (original specification page 5, line 3; FIGS. 2-5) adapted to hold a liquid 11 (specification page 5, line 3; FIGS. 2 & 3) and having an axially outwardly open end 1a (specification page 5, line 5; FIG. 2 only);

an inner cap 2 (specification page 5, line 6; FIGS. 1-5) fitted over the body end 1a;

an axially extending needle 3 (specification page 5, line 8; FIGS. 1-5) seated in the inner cap 2 and having an outer point 15 (specification page 5, line 10; FIG. 1 only) projecting axially outward from the inner cap 2 and an inner point 6 (specification page 5, line 9; FIG. 1 only) projecting axially inward from the inner cap 2 toward the body 1;

a washer 4 (specification page 5, line 14; FIGS. 1-5) between the inner cap 2 and the body end 1a, having a central hole into which the inner point 6 of the needle 3 engages, and provided with a membrane 5 (specification page 5, line 16; FIG. 1) closing the hole and spaced axially inward from the inner point 6 and out of engagement with the needle 3;

an outer cap 8 (specification page 5, line 19; FIGS. 1-5) fittable over the inner cap 2 and needle 3;

a clamp ring 9 (specification page 5, line 19; FIGS 1-5) engageable around the inner cap 2;

a frangible web 10 (specification page 5, line 21; FIGS 1-5) connecting the ring 9 to the outer cap 8; and

interengaging formations 9a, 2c, 2d (specification page 5, lines 11-13; FIGS. 1-3) on the ring 9 and on the inner cap 2 for releasably retaining the outer cap 8 in an outer position (FIG. 3) spaced axially outward of the body 1 and in which an interior of the outer cap 8 is open to the exterior and an inner position (FIG. 4) spaced axially closely to the body 1 and in which the interior of the outer cap 8 is not open to the exterior.

Furthermore according to the invention and as described in the dependent claims there is a rubber liner cup 12 inside the outer cap 8, receiving the outer point 15 of the needle 3, and clamped in the inner position between the outer cap 8 and the inner cap 2. The inner cap 2 is formed with a central outwardly extending projection 13 from which the needle 3 extends axially

outward and that fits snugly in the liner cup 12 in the inner position.

These parts can be put together into the FIG. 3 position and then autoclaved. Simply shifting them into the FIG. 4 position then makes the assembly into something that is internally sterilized and that can be handled with ease. All the parts are easily made and, therefore, inexpensive, so that the disposable hypodermic can be made at low cost but will still have the requisite sterility.

#### VI. GROUNDS OF REJECTION

Claims 1, 2, and 4 are rejected under §102 on US 6,186,980 of Brunel.

Claim 3 is rejected under §103 on a combination of Brunel with US patent 5,624,405 of Futagawa.

(Both of the applied references were cited for the first time in the final action along with a list of 41 other patent documents described as being "pertinent" but not listed in a PTO-892 or referred to.)

## VII. ARGUMENTS

Claims 1, 2, and 4:

The rejection on Brunel is based on a misreading of this reference. The single-use syringe of Brunel completely lacks several of the structural features recited in amended claim 1.

More specifically:

1. Presuming that the sleeve 1 is the "body" of claim 1, then the tip 1a, which is a unitary end formation 1a of the body 1, is the "inner cap" of claim 1. The formation or inner cap 1a holds a needle 2 that is not a double-ended needle with "an inner point projecting axially inward from the inner cap." Instead the needle 2 is a standard single-point needle with an inner end apparently imbedded in or flush with the end formation 1a.

2. There is no structure whatsoever comparable with the "washer" of claim 1. If the formation 1a is also the washer, it does not meet the language of claim 1 since it has nothing resembling a membrane closing a hole and "spaced axially inward from the inner point and out of engagement with the needle." The examiner's statement on page 2 of the action that there is "a washer (1a) between the inner cap and the body end, having a central hole into which the inner point of the needle engages, and provided with a membrane (see figure 1) closing the hole and spaced axially inward from the inner point and out of engagement with the needle" is fantasy. There is no such structure. Neither the word "membrane" nor the word "washer" can be found in Brunel. No

membrane structure is illustrated, nor would one serve any function.

3. The "interfitting formations" that "releasably" retain the outer cap on the ring in either an outer or an inner position are seen nowhere in Brunel. Here there is one position, an inner position shown in FIG. 1 and a completely broken-off position shown in FIG. 2. The slidable assembly for protecting the needle shown in FIGS. 13 and 14 is not comparable to the positions of the instant invention. There is absolutely nothing in Brunel to suggest that, even if the end cap 8b is not broken off the sleeve 8 in the outer position the "interior of the outer cap is open to the exterior" in the outer position. In fact the structures of Brunel all appear to be solid sleeves so that the interior is blocked off from the exterior in both the "inner" and "outer" positions of the protective sleeve 8. Specific language in claim 1 is being ignored in the rejection.

Simply put, the rejection is not really based on what Brunel shows or describes, but on a completely wrong interpretation of this reference and/or a reading into this reference of structure or features nowhere shown or suggested by it. Several specifically claimed elements - the inner point of the needle, the membrane, the washer - are not shown or discussed in Brunel and other more functional features - the outer position for opening the interior of the assembly to the exterior - are not suggested. The rejection under §102 has no support whatsoever and, since the missing

structure and function are not suggested, a §103 rejection is similarly out of the question.

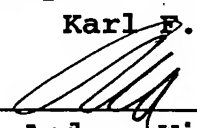
Claim 3:

Futagawa is even further afield. This reference completely lacks any dual-position end parts and does not show a needle, washer, or membrane. This reference is irrelevant to the instant invention.

CONCLUSION

Thus the rejection is based on a misreading of the references. Structure and positions specifically described in the claims is not seen in or suggested by the cited references.

Respectfully submitted,  
Karl P. Ross P.C.

  
by: Andrew Wilford, 26,597  
Attorney for Applicant

28 November 2006  
5676 Riverdale Avenue Box 900  
Bronx, NY 10471-0900  
Cust. No.: 535  
Tel: (718) 884-6600  
Fax: (718) 601-1099

Enclosure:

PTO-2038 for appeal fee (*previously sent*)  
Claim Appendix



## VIII. CLAIM APPENDIX

1           1. A hypodermic syringe comprising:  
2           a hollow body adapted to hold a liquid and having an  
3 axially outwardly open end;  
4           an inner cap fitted over the body end;  
5           an axially extending needle seated in the inner cap and  
6 having an outer point projecting axially outward from the inner cap  
7 and an inner point projecting axially inward from the inner cap  
8 toward the body;  
9           a washer between the inner cap and the body end, having a  
10 central hole into which the inner point of the needle engages, and  
11 provided with a membrane closing the hole and spaced axially inward  
12 from the inner point and out of engagement with the needle;  
13           an outer cap fittable over the inner cap and needle;  
14           a clamp ring engageable around the inner cap;  
15           a frangible web connecting the ring to the outer cap; and  
16           interengaging formations on the ring and on the inner cap  
17 for releasably retaining the outer cap in an outer position spaced  
18 axially outward of the body and in which an interior of the outer cap  
19 is open to the exterior and an inner position spaced axially closely  
20 to the body and in which the interior of the outer cap is not open to  
21 the exterior.

1           2. The hypodermic syringe defined in claim 1, further  
2 comprising  
3           a liner cup inside the outer cap, receiving the outer point  
4 of the needle, and clamped in the inner position between the outer  
5 cap and the inner cap.

1           3. The hypodermic syringe defined in claim 2 wherein the  
2 liner cup is of rubber.

1           4. The hypodermic syringe defined in claim 2 wherein the  
2 inner cap is formed with a central outwardly extending projection  
3 from which the needle extends axially outward and that fits snugly in  
4 the liner cup in the inner position.

IX. EVIDENCE APPENDIX

None.

Atty's 22776

Pat. App. 10/821,253

**X. RELATED PROCEEDINGS**

None.